

CV 16 - 00230

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U.S. DISTRICT COURT
EASTERN DISTRICT
OF NEW YORK

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

ULYANA SHMIDT and JOHN DOES 1-100,
on behalf of themselves and others similarly situated,

Plaintiffs,

Case No.:

CLASS ACTION COMPLAINT

v.

JURY TRIAL DEMANDED

GLASSER, J.

VICTORIA FINE FOODS, LLC,

Defendant.

GO, M.J.

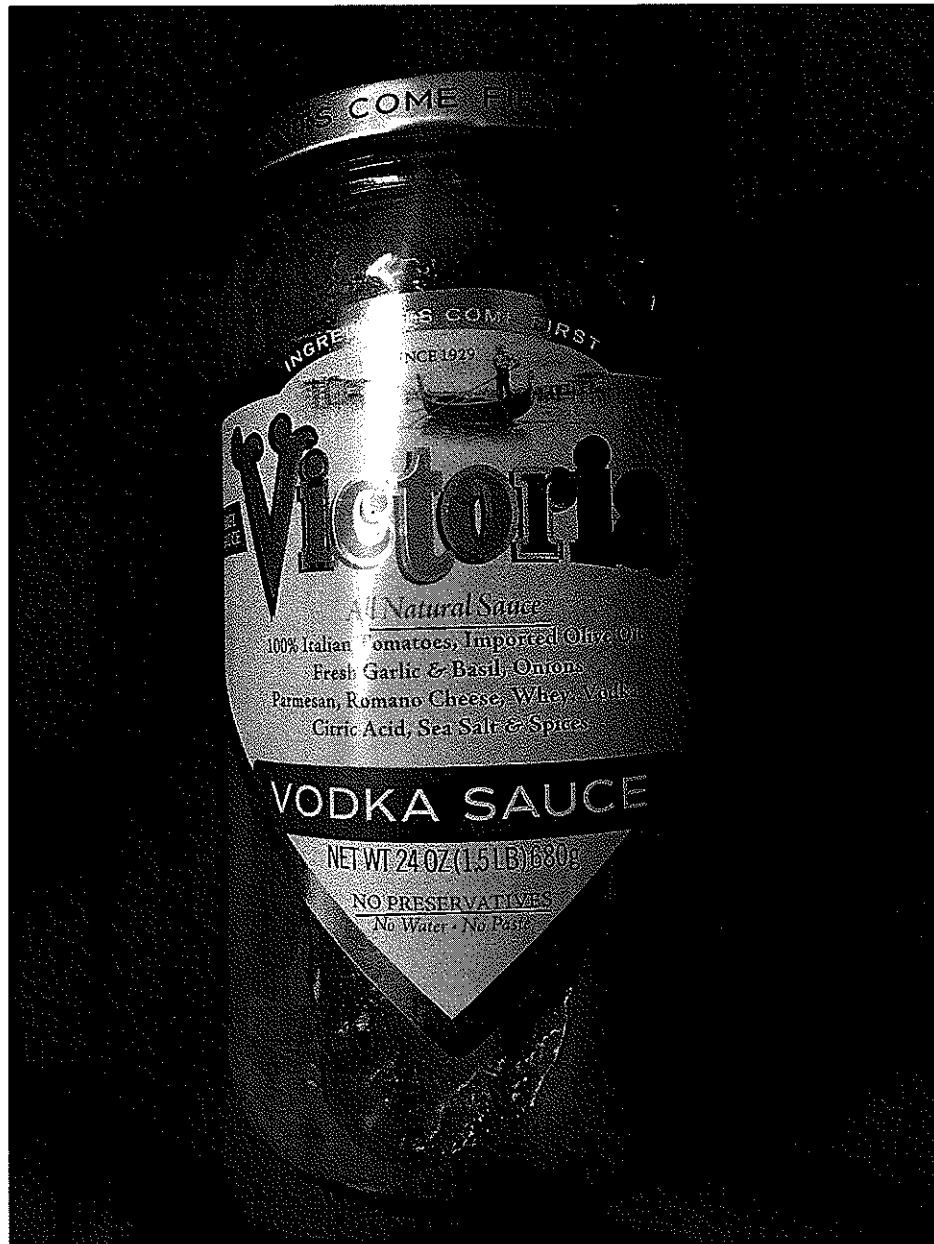
Plaintiffs ULYANA SHMIDT and JOHN DOES 1-100 (together, "Plaintiffs"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, as and for their Complaint against the Defendant, VICTORIA FINE FOODS, LLC, (hereinafter, "VICTORIA FINE FOODS" or "Defendant"), alleges the following based upon personal knowledge as to themselves and their own action, and, as to all other matters, respectfully alleges, upon information and belief, as follows (Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery):

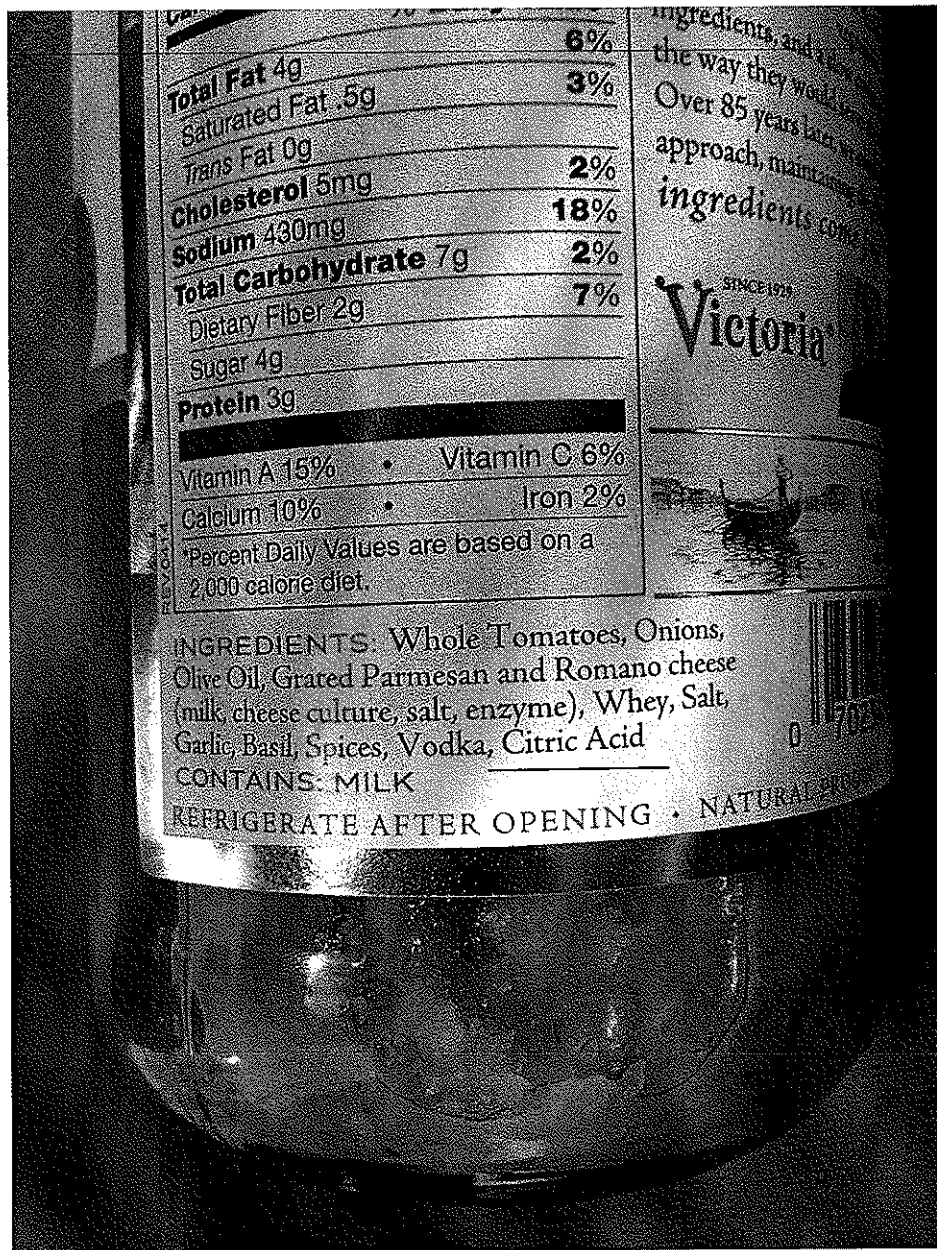
NATURE OF THE ACTION

1. Plaintiffs, ULYANA SHMIDT and JOHN DOES 1-100, on behalf of themselves and others similarly situated, by and through their undersigned attorneys, bring this class action against Defendant, VICTORIA FINE FOODS, LLC, for the deceptive practice of marketing its Victoria® Premium Vodka Sauce product as containing “No Preservatives”¹ when it contains the non-natural, chemically processed ingredient and preservative Citric Acid.

2. This case is about the deceptive manner in which the Defendant marketed its Product (defined below) to the general public during the Class Period.

3. Defendant sold Plaintiffs and Class members, and continues to sell consumers the Victoria® Premium Vodka Sauce with misleading “All Natural” and “No Preservatives” language. The Product’s label is shown below:





4. Consumers attribute a wide range of benefits to foods made entirely of natural ingredients. Consumers perceive all-natural foods to be higher quality, healthier, safer to eat and less damaging to the environment. Defendant profited in this lucrative market for natural foods by misleadingly labeling the Product as containing “No Preservatives” and selling them to consumers who sought to purchase products made from ingredients that are naturally occurring and who were willing to pay more for such foods. Defendant’s Product, however, contained

substantial quantities of the unnatural ingredient and preservative Citric Acid, which is synthetic/non-natural or highly chemically processed.

5. Plaintiffs bring this proposed consumer class action on behalf of themselves and all other persons nationwide, who, from the applicable limitations period up to and including the present (“Class Period”), purchased for consumption and not resale any of Defendant’s Product.

6. Defendant violated statutes enacted in each of the fifty states and the District of Columbia that are designed to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. These statutes are:

- 1) Alabama Deceptive Trade Practices Act, Ala. Statues Ann. §§ 8-19-1, *et seq.*;
- 2) Alaska Unfair Trade Practices and Consumer Protection Act, Ak. Code § 45.50.471, *et seq.*;
- 3) Arizona Consumer Fraud Act, Arizona Revised Statutes, §§ 44-1521, *et seq.*;
- 4) Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, *et seq.*;
- 5) California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*, and California’s Unfair Competition Law, Cal. Bus. & Prof Code § 17200, *et seq.*;
- 6) Colorado Consumer Protection Act, Colo. Rev. Stat. § 6 - 1-101, *et seq.*;
- 7) Connecticut Unfair Trade Practices Act, Conn. Gen. Stat § 42-110a, *et seq.*;
- 8) Delaware Deceptive Trade Practices Act, 6 Del. Code § 2511, *et seq.*;
- 9) District of Columbia Consumer Protection Procedures Act, D.C. Code § 28 3901, *et seq.*;
- 10) Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq.*;
- 11) Georgia Fair Business Practices Act, § 10-1-390 *et seq.*;
- 12) Hawaii Unfair and Deceptive Practices Act, Hawaii Revised Statues § 480 1, *et seq.*, and Hawaii Uniform Deceptive Trade Practices Act, Hawaii Revised Statutes § 481A-1, *et seq.*;
- 13) Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.*;
- 14) Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1, *et seq.*;
- 15) Indiana Deceptive Consumer Sales Act, Indiana Code Ann. §§ 24-5-0.5-0.1, *et seq.*;
- 16) Iowa Consumer Fraud Act, Iowa Code §§ 714.16, *et seq.*;
- 17) Kansas Consumer Protection Act, Kan. Stat. Ann §§ 50 626, *et seq.*;
- 18) Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*, and the Kentucky Unfair Trade Practices Act, Ky. Rev. Stat. Ann §§ 365.020, *et seq.*;
- 19) Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. Ann. § § 51:1401, *et seq.*;
- 20) Maine Unfair Trade Practices Act, 5 Me. Rev. Stat. § 205A, *et seq.*, and Maine Uniform Deceptive Trade Practices Act, Me. Rev. Stat. Ann. 10, § 1211, *et seq.*;
- 21) Maryland Consumer Protection Act, Md. Com. Law Code § 13-101, *et seq.*;
- 22) Massachusetts Unfair and Deceptive Practices Act, Mass. Gen. Laws ch. 93A;
- 23) Michigan Consumer Protection Act, § § 445.901, *et seq.*;
- 24) Minnesota Prevention of Consumer Fraud Act, Minn. Stat §§ 325F.68, *et seq.*; and Minnesota Uniform Deceptive Trade Practices Act, Minn. Stat. § 325D.43, *et seq.*;

- 25) Mississippi Consumer Protection Act, Miss. Code Ann. §§ 75-24-1, *et seq.*;
- 26) Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*;
- 27) Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code §30-14-101, *et seq.*;
- 28) Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59 1601, *et seq.*, and the Nebraska Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301, *et seq.*;
- 29) Nevada Trade Regulation and Practices Act, Nev. Rev. Stat. §§ 598.0903, *et seq.*;
- 30) New Hampshire Consumer Protection Act, N.H. Rev. Stat. § 358-A:1, *et seq.*;
- 31) New Jersey Consumer Fraud Act, N.J. Stat. Ann. §§ 56:8 1, *et seq.*;
- 32) New Mexico Unfair Practices Act, N.M. Stat. Ann. §§ 57 12 1, *et seq.*;
- 33) New York Deceptive Acts and Practices Act, N.Y. Gen. Bus. Law §§ 349, *et seq.*;
- 34) North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51 15 01, *et seq.*;
- 35) North Dakota Consumer Fraud Act, N.D. Cent. Code §§ 51 15 01, *et seq.*;
- 36) North Carolina Unfair and Deceptive Trade Practices Act, North Carolina General Statutes §§ 75-1, *et seq.*;
- 37) Ohio Deceptive Trade Practices Act, Ohio Rev. Code. Ann. §§ 4165.01. *et seq.*;
- 38) Oklahoma Consumer Protection Act, Okla. Stat. 15 § 751, *et seq.*;
- 39) Oregon Unfair Trade Practices Act, Rev. Stat § 646.605, *et seq.*;
- 40) Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Penn. Stat. Ann. § § 201-1, *et seq.*;
- 41) Rhode Island Unfair Trade Practices And Consumer Protection Act, R.I. Gen. Laws § 6-13.1-1, *et seq.*;
- 42) South Carolina Unfair Trade Practices Act, S.C. Code Laws § 39-5-10, *et seq.*;
- 43) South Dakota's Deceptive Trade Practices and Consumer Protection Law, S.D. Codified Laws §§ 37 24 1, *et seq.*;
- 44) Tennessee Trade Practices Act, Tennessee Code Annotated §§ 47-25-101, *et seq.*;
- 45) Texas Stat. Ann. §§ 17.41, *et seq.*, Texas Deceptive Trade Practices Act, *et seq.*;
- 46) Utah Unfair Practices Act, Utah Code Ann. §§ 13-5-1, *et seq.*;
- 47) Vermont Consumer Fraud Act, Vt. Stat. Ann. tit.9, § 2451, *et seq.*;
- 48) Virginia Consumer Protection Act, Virginia Code Ann. §§59.1-196, *et seq.*;
- 49) Washington Consumer Fraud Act, Wash. Rev. Code § 19.86.010, *et seq.*;
- 50) West Virginia Consumer Credit and Protection Act, West Virginia Code § 46A-6-101, *et seq.*;
- 51) Wisconsin Deceptive Trade Practices Act, Wis. Stat. §§ 100. 18, *et seq.*;
- 52) Wyoming Consumer Protection Act, Wyoming Stat. Ann. §§40-12-101, *et seq.*

7. Defendant marketed its Victoria® Product in a way that is deceptive to consumers under consumer protection laws of all fifty states and the District of Columbia. Defendant has been unjustly enriched as a result of its conduct. For these reasons, Plaintiffs seek the relief set forth herein.

JURISDICTION AND VENUE

8. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332, because this is a class action, as defined by 28 U.S.C § 1332(d)(1)(B), in which a member of the putative

class is a citizen of a different state than Defendant, and the amount in controversy exceeds the sum or value of \$5,000,000, excluding interest and costs. *See* 28 U.S.C. § 1332(d)(2).

9. The Court has jurisdiction over the federal claims alleged herein pursuant to 28 U.S.C. § 1331 because it arises under the laws of the United States.

10. The Court has jurisdiction over the state law claims because they form part of the same case or controversy under Article III of the United States Constitution.

11. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332 because the matter in controversy exceeds the sum or value of \$75,000 and is between citizens of different states.

12. This Court has personal jurisdiction over Plaintiffs because Plaintiffs submit to the Court's jurisdiction. This Court has personal jurisdiction over Defendant, pursuant to New York Statute N.Y. CVP. Law § 302, because they conduct substantial business in this District, some of the actions giving rise to the Complaint took place in this District, and some of Plaintiffs' claims arise out of Defendant operating, conducting, engaging in or carrying on a business or business venture in this state or having an office or agency in this state; committing a tortious act in this state; and causing injury to person or property in this state arising out of Defendant's acts and omissions outside this state. Additionally, this court has personal jurisdiction over Defendant because its Product is advertised, marketed, distributed, and sold throughout New York State; Defendant engaged in the wrongdoing alleged in this Complaint throughout the United States, including in New York State; and Defendant has sufficient minimum contacts with New York and/or otherwise have intentionally availed themselves of the markets in New York State, rendering the exercise of jurisdiction by the Court permissible under traditional notions of fair

play and substantial justice. Moreover, Defendant is engaged in substantial and not isolated activity within New York State.

13. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to these claims occurred in this District, the Defendant has caused harm to class members residing in this District, and the Defendant is a resident of this District under 28 U.S.C. 1391(c)(2) because they are subject to personal jurisdiction in this district.

PARTIES

Plaintiffs

14. Plaintiff ULYANA SHMIDT is, and at all times relevant hereto has been, a citizen of the State of New York and resides in Kings County. During the Class Period, Plaintiff SHMIDT purchased the Product for personal consumption within the State of New York. Plaintiff purchased the Product from a Stop&Shop store located in Kings County. The purchase price was \$6.99 (or more) for an individual Product. Plaintiff SHMIDT purchased the Product at a premium price and was financially injured as a result of Defendant's deceptive conduct as alleged herein. Further, should Plaintiff SHMIDT encounter the Product in the future, she could not rely on the truthfulness of the packaging, absent corrective changes to the packaging. However, Plaintiff SHMIDT would still be willing to purchase the current formulation of the Product, absent the price premium, so long as Defendant engage in corrective advertising.

15. Plaintiffs JOHN DOES 1-100 are, and at all times relevant hereto has been, citizens of the any of the fifty states and the District of Columbia. During the Class Period, Plaintiffs JOHN DOES 1-100 purchased the Product for personal consumption or household use within the

United States. Plaintiffs purchased the Product at a premium price and were financially injured as a result of Defendant's deceptive conduct as alleged herein.

Defendant

16. Defendant VICTORIA FINE FOODS, LLC is a corporation organized under the laws of Delaware with its headquarters at Victoria Fine Foods, 443 East 100th Street, Brooklyn, New York 11236 and an address for service of process located at the Corporation Service Company, 2711 Centerville Rd. Suite 400, Wilmington, DE 19808.

17. Defendant develops, markets and sells food products under the "Victoria®" brand name throughout the United States. The advertising for the Product, relied upon by Plaintiffs, was prepared and/or approved by Defendant and its agents, and was disseminated by Defendant and its agents through advertising containing the misrepresentations alleged herein. The advertising for the Product was designed to encourage consumers to purchase the Product and reasonably misled the reasonable consumer, i.e. Plaintiffs and the Class, into purchasing the Product. Defendant owns, manufactures and distributes the Product, and created and/or authorized the unlawful, fraudulent, unfair, misleading and/or deceptive labeling and advertising for the Product.

FACTUAL ALLEGATIONS

Victoria® Vodka All Natural Sauce


18. Defendant manufacture, market, advertise and sell its extensive "Victoria®" line of pasta sauce products across the United States.

19. Defendant markets numerous products under its "Victoria®" brand such as the Product purchased by Plaintiffs. The Product is available at numerous retail and online outlets such as Stop&Shop, Shoprite, Target and Amazon.com.

20. The official Victoria® website displays the entirety of its “Victoria®” pasta sauce product line with brief product descriptions and full lists of ingredients on each product page. The image on Product’s page demonstrates that it is meant to be “All Natural” and contain “No Preservatives,” as shown below:

INGREDIENTS COME FIRST

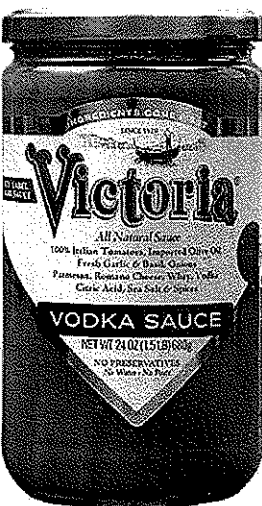
SINCE 1929



OUR PRODUCTS • COMPARE YOUR BRAND

ARTISINAL APPROACH • ABOUT US

Victoria Premium
Vodka Sauce – 24oz



Rich, creamy and perhaps a bit sinful, our Vodka Sauce will elevate your palate to a place of incomparable culinary pleasure. With Romano and Parmesan cheeses and just enough good quality vodka added to our Classic Marinara base, it's no wonder this is one of our most popular flavors.

INGREDIENTS: WHOLE TOMATOES, ONIONS, OLIVE OIL, GRATED PARMESAN AND ROMANO CHEESE (MILK, CHEESE, CULTURE, SALT, ENZYME), WHEY, SALT, GARLIC, BASIL, SPICES, VODKA, CITRIC ACID

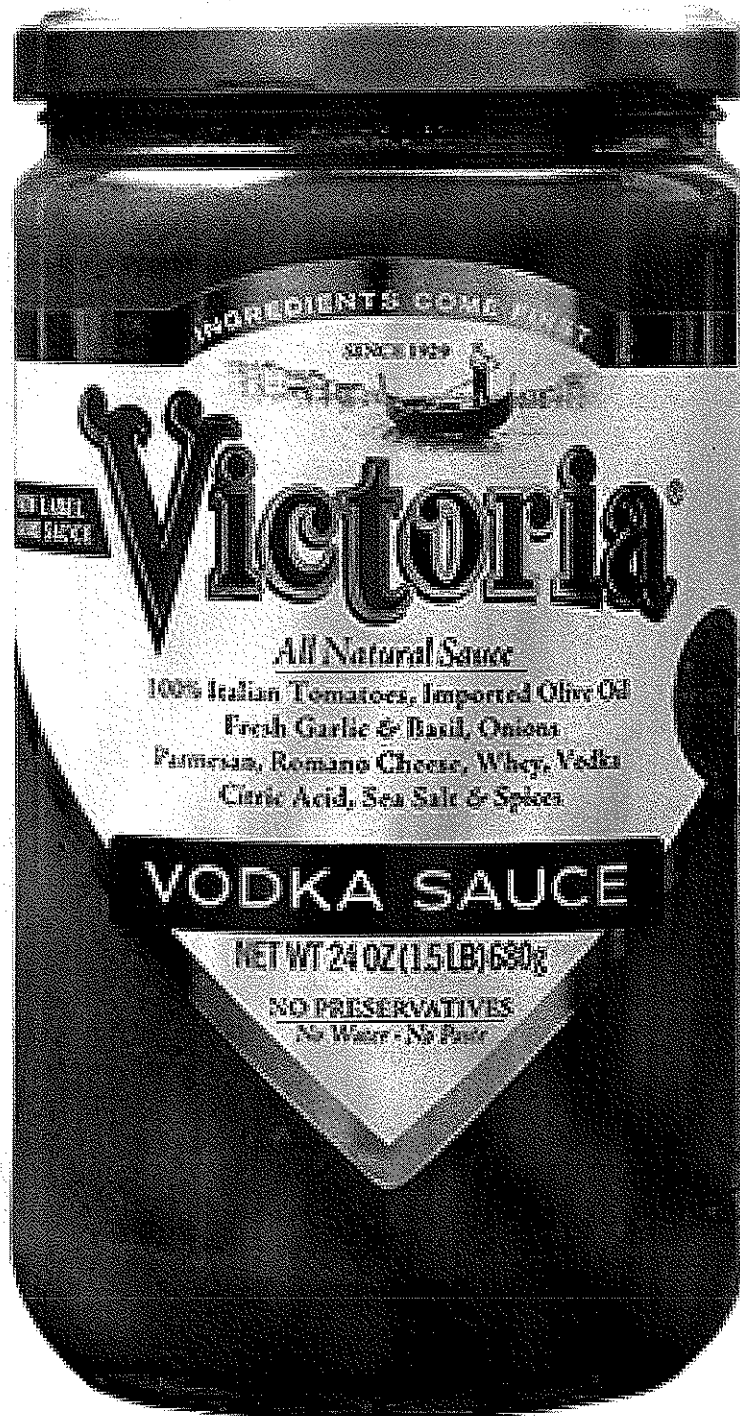
Victoria Premium Vodka Sauce is gluten free, kosher, vegetarian, no added sugar, peanut free, soy free, shellfish free and tree nut free.

Nutrition Facts

Serving Size 1/2 Cup (113g)
Serving Per Container About 6

Amount Per Serving	
Calories 80	Calories From Fat 35
% Daily Value*	
Total Fat 4g	6%
Saturated Fat .5g	3%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 430mg	18%
Total Carbohydrate 7g	2%
Dietary Fiber 2g	7%
Sugar 4g	
Protein 3g	
Vitamin A 15%	Vitamin C 6%
Calcium 10%	Iron 2%

*Percent Daily Values are based on a 2,000 calorie diet.



21. By representing that the Product was "All Natural" and contained "No Preservatives," Defendant sought to capitalize on consumers' preference for natural products and

the association between such products and a wholesome way of life. Consumers are willing to pay more for natural products because of this association as well as the perceived higher quality, health and safety benefits and low impact on the environment associated with products labeled as “Natural.”

22. As a result of Defendant’s deception, consumers – including Plaintiffs and members of the proposed Class – have purchased a Product that contains a synthetic or highly chemically processed ingredient in reliance on Defendant’s “All Natural” and “No Preservative” claims. Moreover, Plaintiffs and Class members have paid a premium for the Product over other similar pasta sauce products sold on the market. A sample of other similar pasta sauce products are provided below:

<u>BRAND</u>	<u>PRICE</u>	<u>SELLER</u>
Bertolli Vodka Sauce, 24 Ounce Jar	\$2.65	Jet.com
Newman's Own Marinara Sauce, 24 Ounce	\$4.39	Jet.com
Victoria Pasta Sauce Vodka, 25 oz	\$6.99	Shop&Stop

Definition of Natural

23. The FDA did not intend to and has repeatedly declined to establish a final rule with regard to a definition of the term “natural” in the context of food labeling. As such, Plaintiffs’ state consumer protection law claims are not preempted by federal regulations. See *Jones v. ConAgra Foods, Inc.*, 2012 WL 6569393, *6 (N.D. Cal. Dec. 17, 2012). Additionally, the primary jurisdiction doctrine does not apply “because the FDA has repeatedly declined to adopt formal rule-making that would define the word ‘natural.’” *Id.* at p. 8.

24. The “FDA has not developed a definition for use of the term natural or its derivatives,” but it has loosely defined the term “natural” as a product that “does not contain added color, artificial flavors, or synthetic substances.” According to federal regulations, an ingredient is synthetic if it is:

[a] substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. 7 C.F.R. §205.2.

25. Although there is not an exacting definition of “natural” in reference to food, ingredients, there is no reasonable definition of “natural” that includes ingredients that, even if sourced from “nature,” are subjected to extensive transformative chemical processing before their inclusion in a product. For example, the National Advertising Division of the Better Business Bureau (“NAD”) has found that a “natural” ingredient does not include one that, while “literally sourced in nature (as is every chemical substance), . . . is, nevertheless subjected to extensive processing before metamorphosing into the” ingredient that is included in the final product.

26. Along the same lines, the United States Department of Agriculture (“USDA”) has issued a Foods Standards and Labeling Policy Book (Aug. 2005), which states that the term “natural” may be used on labeling for products that contain processed ingredients only where such ingredients are subjected to “minimal” processing and that relatively severe processes, e.g., solvent extraction, acid hydrolysis and chemical bleaching would clearly be considered more than minimal processing. In regulating the National Organic Program, the USDA likewise defines “nonsynthetic (natural)” as “[a] substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process. . .” 7 C.F.R. § 205.2. In contrast, “synthetic” means “a substance that is formulated or manufactured by a chemical process or by a process

that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources. . . .” 7 U.S.C. § 6502 (21).

Citric Acid in Defendant’s Products

27. The Product was labeled “All Natural” and “No Preservatives” yet contain the synthetic, non-natural and extensively processed ingredient Citric Acid.

28. The “All Natural” ingredients and “No Preservatives” claims appear on the label and website page of the Product.

29. Within the last twelve months, Plaintiffs purchased the Victoria® Product. Plaintiffs were attracted to this Product because they prefer to consume and use natural products for health reasons. Plaintiffs believe that all natural products contain only ingredients that occur in nature or are minimally processed and that they would not include Citric Acid amongst such ingredients. As a result, the Product with its deceptive “All Natural” claims on the Product packaging had no value to Plaintiffs. Defendant marketed the Product as “All Natural” and contained “No Preservatives” to induce consumers to purchase the Product.

Citric Acid Is Not a Natural Ingredient

30. Citric acid (2-hydroxy-propane-1,2,3-tricarboxylic acid) is a synthetic, non-natural ingredient. While the chemical’s name has the word “citric” in it, citric acid is no longer extracted from the citrus fruit but industrially manufactured by fermenting certain genetically mutant strains of the black mold fungus, *Aspergillus niger*.

31. A technical evaluation report for the substance citric acid compiled by the United States Department of Agriculture, Agricultural Marketing Service (“USDA AMS”) for the National Organic Program classified citric acid as “Synthetic Allowed”. See **EXHIBIT A**, Page

4, available at <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5067876>. As one of the USDA AMS reviewers commented,

“[Citric acid] is a natural[ly] occurring substance that commercially goes through numerous chemical processes to get to [its] final usable form. This processing would suggest that it be classified as synthetic.” Id. at 3.

The report further explains, under the “How Made” question, that citric acid is made –

“Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, *Aspergillus niger* (a mold) or *Candida guilliermondii* (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid.” Id. at 4.

32. Because Citric Acid is a synthetic acid and cannot be reasonably considered a natural ingredient, Defendants’ claim that the Products are “All Natural” is false, deceptive, and misleading, and the Products are misbranded under federal and state law.

Citric Acid Is a Preservative

33. While the acidic pH of citric acid would most certainly provide tartness to the Products, such explanation is pretextual because the real function of the citric acid in the Products is as a preservative.

34. The U.S. Food and Drug Administration (“FDA”) routinely required that food manufacturers disclose the fact that citric acid is used as a preservative. In a Warning Letter dated October 6, 2010, the FDA warned the manufacturers of the Chiquita brand “Pineapple Bites with Coconut” and “Pineapple Bites” products, that they are in violation of the FDCA and the federal regulations promulgated pursuant to the FDCA:

“The ‘Pineapple Bites’ and ‘Pineapple Bites with Coconut’ products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22.”

See **EXHIBIT B**, FDA Warning Letter dated October 6, 2010 (emphasis added).

35. Defendants' misleading labeling practices go even further. Apart from not having disclosed the function of the citric acid, Defendants expressly labeled the Products as, check mark, "No Preservatives," even though such was patently false.

36. Because the Products similarly contain citric acid and Defendants similarly "fail[ed] to declare [such] preservative with a description of [its] functions," see *id.*, and because the Products are expressly labeled as containing "No Preservatives," the Products are misbranded food under the FDCA and state laws which incorporate by reference federal food labeling regulations. 21 U.S.C. §§ 343(a)(1), 343(k); N.Y. Agm. Law § 201; California Health and Safety Code §§ 110660, 110740.

The Federal Food, Drug, and Cosmetic Act

37. The Federal Food, Drug, and Cosmetic Act (hereinafter, "FDCA"), 21 U.S.C. §§ 301 *et. seq.*, governs the sale of foods, drugs, and cosmetics in the United States. The classification of a product as a food, drug, or cosmetic affects the regulations by which the product must abide. In general, a product is characterized according to its intended use, which may be established, among other ways, by: (a) claims stated on the product's labeling, in advertising, on the Internet, or in other promotional materials; (b) consumer perception established through the product's reputation, for example by asking why the consumer is buying it and what the consumer expects it to do; or (c) the inclusion of ingredients well-known to have therapeutic use, for example fluoride in toothpaste.

38. Food manufacturers must comply with federal and state laws and regulations governing labeling food products. Among these are the Federal Food, Drug and Cosmetic Act and its labeling regulations, including those set forth in 21 C.F.R. part 101.

39. Under the FDCA, the term “false” has its usual meaning of “untruthful,” while the term “misleading” is a term of art. Misbranding reaches not only false claims, but also those claims that might be technically true, although still misleading. If any one representation in the labeling is misleading, the entire food is misbranded. No other statement in the labeling cures a misleading statement. “Misleading” is judged in reference to “the ignorant, the unthinking and the credulous who, when making a purchase, do not stop to analyze.” *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually misled. New York law similarly does not require proof of actual reliance. *See Pelman ex rel. Pelman v. McDonald's Corp.*, 396 F. Supp. 2d 439, 445 (S.D.N.Y. 2005).

40. New York and federal law have placed similar requirements on food companies that are designed to ensure that the claims companies are making about their products to consumers are truthful and accurate.

41. Defendant’s labeling and advertising of the Product violate various state laws against misbranding. New York State law broadly prohibits the misbranding of food in language identical to that found in regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.:

Pursuant to N.Y. State Education Law § 6815, “[f]ood shall be deemed to be misbranded: 1. If its labeling is false or misleading in any particular...”

42. Defendant’s Product was misbranded under New York law because it misled Plaintiff and Class members about the naturalness of the Product.

43. Although Defendant marketed the Product as “All Natural” and containing “No Preservatives,” it failed to also disclose material information about the Product; the fact that it contained an unnatural, synthetic, and/or artificial ingredient. This non-disclosure, while at the

same time branding the Product as “All Natural” and containing “No Preservatives” was deceptive and likely to mislead a reasonable consumer.

44. A representation that a product is “All Natural” and contains “No Preservatives” is material to a reasonable consumer when deciding to purchase a product. According to Consumers Union, “Eighty-six percent of consumers expect a ‘natural’ label to mean processed foods do not contain any artificial ingredients.”⁴

45. Plaintiffs did, and a reasonable consumer would, attach importance to whether Defendant’s Product is “misbranded,” i.e., not legally salable, or capable of legal possession, and/or contain highly processed ingredients.

46. Plaintiffs did not know, and had no reason to know, that the Product was not “All Natural” and “No Preservatives.”

47. Defendant’s Product labeling and misleading website was a material factor in Plaintiffs’ and Class members’ decisions to purchase the Product. Relying on Defendant’s Product labeling and misleading website, Plaintiffs and Class members believed that they were getting Product that was “All Natural” and contained “No Preservatives.” Had Plaintiffs known Defendant’s Product was highly processed, they would not have purchased it.

48. Defendant’s Product labeling as alleged herein is deceptive and misleading and was designed to increase sales of the Product. Defendant’s misrepresentations are part of its systematic Product packaging practice.

49. At the point of sale, Plaintiffs and Class members did not know, and had no reason to know, that the Product was misbranded as set forth herein, and would not have bought the Product had they known the truth about it.

⁴ Notice of the Federal Trade Commission, Comments of Consumers Union on Proposed Guides for Use of Environmental Marketing Claims, 16 CFR § 260, Dec. 10, 2010, <http://www.ftc.gov/os/comments/greenguidererevisions/00289-57072.pdf> (last visited August 9, 2014).

50. Defendant's false and deceptive labeling is misleading and in violation of FDA and consumer protection laws of each of the fifty states and the District of Columbia, and the Product at issue is misbranded as a matter of law. Misbranded products cannot be legally manufactured, advertised, distributed, held or sold in the United States. Plaintiffs and Class members would not have bought the Product had they known they were misbranded and illegal to sell or possess.

51. As a result of Defendant's misrepresentations, Plaintiffs and thousands of others throughout the United States purchased the Product.

52. Plaintiffs and the Class (defined below) have been damaged by Defendant's deceptive and unfair conduct in that they purchased Product with false and deceptive labeling and paid premium prices they otherwise would not have paid over other comparable products that did not claim to be "All Natural" and contain "No Preservatives."

CLASS ACTION ALLEGATIONS

The Nationwide Class

53. Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of the following class (the "Class"):

All persons or entities in the United States who made retail purchases of the Product during the applicable limitations period, and/or such subclasses as the Court may deem appropriate.

The New York Class

54. Plaintiff SHMIDT seeks to represent a class consisting of the following subclass (the "New York Class"):

All New York residents who made retail purchases of the Products during the applicable limitations period, and/or such subclasses as the Court may deem appropriate.

The proposed Classes exclude current and former officers and directors of Defendant, members of the immediate families of the officers and directors of Defendant, Defendant's legal representatives, heirs, successors, assigns, and any entity in which they have or have had a controlling interest, and the judicial officer to whom this lawsuit is assigned.

55. Plaintiffs reserve the right to revise the Class definition based on facts learned in the course of litigating this matter.

56. This action is proper for class treatment under Rules 23(b)(1)(B) and 23(b)(3) of the Federal Rules of Civil Procedure. While the exact number and identities of other Class members are unknown to Plaintiffs at this time, Plaintiffs are informed and believe that there are thousands of Class members. Thus, the Class is so numerous that individual joinder of all Class members is impracticable.

57. Questions of law and fact arise from Defendant's conduct described herein. Such questions are common to all Class members and predominate over any questions affecting only individual Class members and include:

- a. whether labeling "All Natural" and "No Preservatives" on the Product containing the synthetic or highly processed ingredient Citric Acid was false and misleading;
- b. whether Defendant engaged in a marketing practice intended to deceive consumers by labeling "All Natural" and "No Preservatives" on the Product containing the synthetic or highly processed ingredient Citric Acid;
- c. whether Defendant deprived Plaintiffs and the Class of the benefit of the bargain because the Product purchased was different than what Defendant warranted;

- d. whether Defendant deprived Plaintiffs and the Class of the benefit of the bargain because the Product they purchased had less value than what was represented by Defendant;
- e. whether Defendant caused Plaintiffs and the Class to purchase a substance that was other than what was represented by Defendant;
- f. whether Defendant caused Plaintiffs and the Class to purchase a Product that was artificial, synthetic, or otherwise unnatural;
- g. whether Defendant has been unjustly enriched at the expense of Plaintiffs and other Class members by its misconduct;
- h. whether Defendant must disgorge any and all profits they have made as a result of its misconduct; and
- i. whether Defendant should be barred from marketing the Product as “All Natural” and containing “No Preservatives.”

58. Plaintiffs’ claims are typical of those of the Class members because Plaintiffs and the other Class members sustained damages arising out of the same wrongful conduct, as detailed herein. Plaintiffs purchased Defendant’s Product and sustained similar injuries arising out of Defendant’s conduct in violation of New York State law. Defendant’s unlawful, unfair and fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. The injuries of the Class were caused directly by Defendant’s wrongful misconduct. In addition, the factual underpinning of Defendant’s misconduct is common to all Class members and represents a common thread of misconduct resulting in injury to all members of the Class. Plaintiffs’ claims arise from the same practices and course of

conduct that give rise to the claims of the members of the Class and are based on the same legal theories.

59. Plaintiffs will fairly and adequately represent and pursue the interests of the Class and have retained competent counsel experienced in prosecuting nationwide class actions. Plaintiffs understand the nature of their claims herein, have no disqualifying conditions, and will vigorously represent the interests of the Class. Neither Plaintiffs nor Plaintiffs' counsel have any interests that conflict with or are antagonistic to the interests of the Class. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and those of the Class. Plaintiffs and Plaintiffs' counsel have the necessary financial resources to adequately and vigorously litigate this class action, and Plaintiffs and counsel are aware of their fiduciary responsibilities to the Class and will diligently discharge those duties by vigorously seeking the maximum possible recovery for the Class.

60. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The damages suffered by any individual class member are too small to make it economically feasible for an individual class member to prosecute a separate action, and it is desirable for judicial efficiency to concentrate the litigation of the claims in this forum. Furthermore, the adjudication of this controversy through a class action will avoid the potentially inconsistent and conflicting adjudications of the claims asserted herein. There will be no difficulty in the management of this action as a class action.

61. The prerequisites to maintaining a class action for injunctive relief or equitable relief pursuant to Rule 23(b)(2) are met, as Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.

62. The prerequisites to maintaining a class action for injunctive relief or equitable relief pursuant to Rule 23(b)(3) are met, as questions of law or fact common to the Class predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

63. The prosecution of separate actions by members of the Class would create a risk of establishing inconsistent rulings and/or incompatible standards of conduct for Defendant. Additionally, individual actions may be dispositive of the interest of all members of the Class, although certain Class members are not parties to such actions.

64. Defendant's conduct is generally applicable to the Class as a whole and Plaintiffs seek, *inter alia*, equitable remedies with respect to the Class as a whole. As such, Defendant's systematic policies and practices make declaratory relief with respect to the Class as a whole appropriate.

CAUSES OF ACTION

COUNT I

INJUNCTION FOR VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 349 (DECEPTIVE AND UNFAIR TRADE PRACTICES ACT)

65. Plaintiff SHMIDT realleges and incorporates herein by reference the allegations contained in all preceding paragraphs, and further alleges as follows:

66. Plaintiff SHMIDT brings this claim on behalf of herself and the other members of the Class for an injunction for violations of New York's Deceptive Acts or Practices Law, Gen. Bus. Law § 349 ("NY GBL").

67. NY GBL § 349 provides that "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are . . . unlawful."

68. Under the § 349, it is not necessary to prove justifiable reliance. (“To the extent that the Appellate Division order imposed a reliance requirement on General Business Law [§] 349 ... claims, it was error. Justifiable reliance by the plaintiff is not an element of the statutory claim.” *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (N.Y. App. Div. 2012) (internal citations omitted)).

69. Any person who has been injured by reason of any violation of the NY GBL may bring an action in their own name to enjoin such unlawful act or practice, an action to recover their actual damages or fifty dollars, whichever is greater, or both such actions. The court may, in its discretion, increase the award of damages to an amount not to exceed three times the actual damages up to one thousand dollars, if the court finds the Defendant willfully or knowingly violated this section. The court may award reasonable attorney's fees to a prevailing plaintiff.

70. The practices employed by Defendant, whereby Defendant advertised, promoted, and marketed that its Product is “All Natural” and contains “No Preservatives” were unfair, deceptive, and misleading and are in violation of the NY GBL § 349.

71. The foregoing deceptive acts and practices were directed at customers.

72. Defendant should be enjoined from marketing its Product as “All Natural” and containing “No Preservatives” as described above pursuant to NY GBL § 349.

73. Plaintiff SHMIDT, on behalf of herself and all others similarly situated, respectfully demands a judgment enjoining Defendant's conduct, awarding costs of this proceeding and attorneys' fees, as provided by NY GBL, and such other relief as this Court deems just and proper.

COUNT II

**VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 349
(DECEPTIVE AND UNFAIR TRADE PRACTICES ACT)**

74. Plaintiff SHMIDT realleges and incorporates herein by reference the allegations contained in all preceding paragraphs, and further alleges as follows:

75. Plaintiff SHMIDT brings this claim individually and on behalf of the other members of the Class for violations of NY GBL § 349.

76. Defendant's business act and practices and/or omissions alleged herein constitute deceptive acts or practices under NY GBL § 349, which were enacted to protect the consuming public from those who engage in unconscionable, deceptive or unfair acts or practices in the conduct of any business, trade or commerce.

77. The practices of Defendant described throughout this Complaint, were specifically directed to consumers and violate the NY GBL § 349 for, inter alia, one or more of the following reasons:

- a. Defendant engaged in deceptive, unfair and unconscionable commercial practices in failing to reveal material facts and information about the Product, which did, or tended to, mislead Plaintiff and the Class about facts that could not reasonably be known by them;
- b. Defendant knowingly and falsely represented and advertised that the Product have "All Natural" ingredients and "No Preservatives" with an intent to cause Plaintiff and members of the Class to believe that they are made with unadulterated, unprocessed ingredients, even though they are not;
- c. Defendant failed to reveal facts that were material to the transactions in light of representations of fact made in a positive manner;

- d. Defendant caused Plaintiff and the Class to suffer a probability of confusion and a misunderstanding of legal rights, obligations and/or remedies by and through its conduct;
- e. Defendant failed to reveal material facts to Plaintiff and the Class with the intent that Plaintiff and the Class members rely upon the omission;
- f. Defendant made material representations and statements of fact to Plaintiffs and the Class that resulted in Plaintiff and the Class reasonably believing the represented or suggested state of affairs to be other than what they actually were; and
- g. Defendant intended that Plaintiff and the members of the Class rely on its misrepresentations and omissions, so that Plaintiff and Class members would purchase the Product.

78. The practices employed by Defendant, whereby Defendant advertised, promoted, and marketed that its Product contains “All Natural” ingredients and “No Preservatives” were unfair, deceptive, and misleading and are in violation of NY GBL § 349.

79. Under all of the circumstances, Defendant’s conduct in employing these unfair and deceptive trade practices was malicious, willful, wanton and outrageous such as to shock the conscience of the community and warrant the imposition of punitive damages.

80. Defendant’s actions impact the public interest because Plaintiff and members of the Class were injured in exactly the same way as thousands of others purchasing the Product as a result of and pursuant to Defendant’s generalized course of deception.

81. By committing the acts alleged in this Complaint, Defendant has misled Plaintiff and the Class into purchasing the Product, in part or in whole, due to an erroneous belief that the

Product contains “All Natural” ingredients and “No Preservatives”. This is a deceptive business practice that violates NY GBL § 349.

82. Defendant’s “All Natural” ingredients and “No Preservatives” claims misled Plaintiff, and are likely in the future to mislead reasonable consumers. Had Plaintiff and members of the Class known of the true facts about the Product, they would not have purchased the Product and/or paid substantially less for similar products.

83. The foregoing deceptive acts, omissions and practices were directed at consumers.

84. The foregoing deceptive acts, omissions and practices set forth in connection with Defendant’s violations of NY GBL § 349 proximately caused Plaintiff and other members of the Class to suffer actual damages in the form of, *inter alia*, monies spent to purchase the Product. Plaintiff and other members of the Class are entitled to recover such damages, together with equitable and declaratory relief, appropriate damages, including punitive damages, attorneys’ fees and costs.

COUNT III

NEGLIGENT MISREPRESENTATION (All States)

85. Plaintiffs reallege and incorporate herein by reference the allegations contained in all preceding paragraphs, and further allege as follows:

86. Defendant, directly or through its agents and employees, made false representations, concealments, and nondisclosures to Plaintiffs and members of the Class.

87. In making the representations of fact to Plaintiffs and members of the Class described herein, Defendant has failed to fulfill its duties to disclose the material facts set forth above. The direct and proximate cause of this failure to disclose was Defendant’s negligence and carelessness.

88. Defendant, in making the misrepresentations and omissions, and in doing the acts alleged above, knew or reasonably should have known that the representations were not true. Defendant made and intended the misrepresentations to induce the reliance of Plaintiffs and members of the Class.

89. Plaintiffs and members of the Class relied upon these false representations and nondisclosures by Defendant when purchasing the Product, which reliance was justified and reasonably foreseeable.

90. As a result of Defendant's wrongful conduct, Plaintiffs and members of the Class have suffered and continue to suffer economic losses and other general and specific damages, including but not limited to the amounts paid for the Product, and any interest that would have been accrued on those monies, all in an amount to be determined according to proof at time of trial.

COUNT IV

BREACH OF EXPRESS WARRANTIES (All States)

91. Plaintiffs reallege and incorporate herein by reference the allegations contained in all preceding paragraphs, and further allege as follows:

92. Defendant provided Plaintiffs and other members of the Class with written express warranties, including, but not limited to, warranties that the Product contain natural or all-natural ingredients and no preservatives. The natural claims made by Defendant are an affirmation of fact that became part of the basis of the bargain and created an express warranty that the good would conform to the stated promise. Plaintiffs placed importance on Defendant's natural claims.

93. Defendant breached the terms of this contract, including the express warranties, with Plaintiffs and the Class by not providing Product with the natures and quality as promised.

94. As a proximate result of Defendant's breach of warranties, Plaintiffs and Class members have suffered damages in an amount to be determined by the Court and/or jury, in that, among other things, they purchased and paid for the Victoria® Product that did not conform to what Defendant promised in its promotion, marketing, advertising, packaging and labeling, and they were deprived of the benefit of their bargain and spent money on the Victoria® Product that did not have any value or had less value than warranted or products that they would not have purchased and used had they known the true facts about them.

COUNT V

UNJUST ENRICHMENT (All States)

95. Plaintiffs reallege and incorporate herein by reference the allegations contained in all preceding paragraphs, and further allege as follows:

96. Defendant received certain monies as a result of its uniform deceptive marketing of the Product that are excessive and unreasonable.

97. Plaintiffs and the Class conferred a benefit on Defendant through purchasing the Product, and Defendant has knowledge of this benefit and have voluntarily accepted and retained the benefits conferred on them.

98. Defendant will be unjustly enriched if it is allowed to retain such funds, and each Class member is entitled to an amount equal to the amount they enriched Defendant and for which Defendant has been unjustly enriched.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of all other similarly situated, seek judgment against Defendant, as follows:

- a. An Order that this action be maintained as a class action and appointing Plaintiffs as representatives of the Nationwide Class and/or their respective state Class;
- b. An Order appointing the undersigned attorney as class counsel in this action;
- c. Restitution and disgorgement of all amounts obtained by Defendant as a result of its misconduct, together with interest thereon from the date of payment, to the victims of such violations;
- d. All recoverable compensatory and other damages sustained by Plaintiffs and the Class;
- e. Actual and/or statutory damages for injuries suffered by Plaintiffs and the Class and in the maximum amount permitted by applicable law;
- f. An order (i) requiring Defendant to immediately cease its wrongful conduct as set forth in this Complaint; (ii) enjoining Defendant from continuing to misrepresent and conceal material information and conduct business via the unlawful, unfair and deceptive business acts and practices complained of herein; (iii) ordering Defendant to engage in a corrective advertising campaign; and (iv) requiring Defendant to reimburse Plaintiffs and all members of the Class the amounts paid for the Product;
- g. Statutory pre-judgment and post-judgment interest on any amounts;
- h. Payment of reasonable attorneys' fees and costs; and
- i. Such other relief as the Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and all others similarly situated, demand a trial by jury on all questions of fact raised by the Complaint.

Dated: January 15, 2016

Respectfully submitted,

LEE LITIGATION GROUP, PLLC
C.K. Lee (CL 4086)
Anne Seelig (AS 3976)
30 East 39th Street, Second Floor
New York, NY 10016
Tel.: 212-465-1188
Fax: 212-465-1181
Attorneys for Plaintiffs and the Class

By: 
C.K. Lee, Esq.

EXHIBIT A

Nov 8
Syn 5

allowed

NOSB NATIONAL LIST FILE CHECKLIST

PROCESSING

MATERIAL NAME: Citric Acid

CATEGORY: Synthetic Allowed

Complete?: 3/16

✓

NOSB Database Form

✓

References

✓

MSDS (or equivalent)

✓

FASP (FDA)

✓

Date file mailed out: 1/8/95

✓

TAP Reviews from: Steve Taylor

Steven Harper

Bob Durst

Supplemental Information:

Microbial form only
because of substrate might be
as product

MISSING INFORMATION: _____

NOSB/NATIONAL LIST COMMENT FORM/BALLOT

Use this page to write down comments and questions regarding the data presented in the file of this National List material. Also record your planned opinion/vote to save time at the meeting on the National List.

Name of Material Citric Acid

Type of Use: ☐ Crops; ☐ Livestock; ☒ Processing

TAP Review by:

1. Steve Taylor
2. Steven Harper
3. Bob Durst

Comments/Questions:

My Opinion/Vote is:

Signature _____ Date _____

1.

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steve Taylor

Is this substance Natural or Synthetic? Explain (if appropriate)

Natural

Please comment on the accuracy of the information in the file:

This material should be added to the National List as:

 Synthetic Allowed Prohibited Natural

or, This material does not belong on the National List because:

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

Made by fermentation. Fermentation is natural but process does ~~any~~ involve use of other substances: Substrates: corn syrup, sucrose
Any additional comments or references? ammonium bicarbonate

Need to find out more about process and processing aids to make determination.

Signature Steve Taylor Date 3-5-95

2.

USDA/TAP REVIEWER COMMENT FORM

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Attach additional sheets if you wish.

This file is due back to us within 30 days of: Jan 7

Name of Material: Citric Acid

Reviewer Name: Steven Harper

Is this substance Natural or Synthetic? Explain (if appropriate)

Synthetic

Please comment on the accuracy of the information in the file:

Good

This material should be added to the National List as:

 x Synthetic Allowed Prohibited Natural

or, This material does not belong on the National List because:

Are there any restrictions or limitations that should be placed on this material by use or application on the National List?

No.

Any additional comments or references?

Signature Steven Harper

Date 3/10/05

USDA/TAP Reviewer Comment Form

3.

Material: Citric acid

Reviewer: Bob Durst

Is this substance Natural or Synthetic? Explain (if appropriate)

It is a natural occurring substance that commercially goes through numerous chemical processes to get to it's final usable form. This processing would suggest that it be classified as synthetic.

Please comment on the accuracy of the information in the file:

The file is accurate.

This material should be added to the National List as:

- ☒ Synthetic Allowed,
☐ Prohibited Natural, or
☐ This material does not belong on the National List because:

Are there any restriction or limitations that should be placed on this material by use or application on the National List?

Must be listed on the ingredient label if it used used.

Unless it is actually derived from a natural source the labeling must not indicate that it is a natural compound.

Any additional comments or references?

As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.

Since citrus juices are a high natural source of citric acid, it might be advisable to find a manufacturer that is willing to isolate citric acid from organically grown fruit in an organically acceptable manner, and get a natural citric acid.

Signature



Date

3/4/95

NOSB Materials Database

4.

Identification

Common Name	Citric Acid	Chemical Name	B-hydroxy-tricarboxylic acid C ₆ H ₈ O ₇
Other Names	Citric Acid, Anhydrous USP/FCC		
Code #: CAS	77-92-9	Code #: Other	21 CFR 182-1033
N. L. Category	Synthetic Allowed	MSDS	<input checked="" type="radio"/> yes <input type="radio"/> no

Chemistry

Family	Aliphatic Acid
Composition	C ₆ H ₈ O ₇
Properties	Colorless, translucent crystals, (or) white granular to fine crystalline powder, odorless, strong acid taste.
How Made	Traditionally by extraction from citrus juice, no longer commercially available. It is now extracted by fermentation of a carbohydrate substrate (often molasses) by citric acid bacteria, <i>Aspergillus niger</i> (a mold) or <i>Candida guilliermondii</i> (a yeast). Citric acid is recovered from the fermentation broth by a lime and sulfuric acid process in which the citric acid is first precipitated as a calcium salt and then reacidulated with sulfuric acid.

Use/Action

Type of Use	Processing
Specific Use(s)	Production of fruit products, juices, oils, fats etc. for pH control, flavor enhancer, flavoring agent or adjuvant, leavening agent, sequestrant, antioxidant, solvent, antimicrobial agent, surface-active agent.
Action	Optimizes stability of frozen foods by enhancing the action of antioxidants and inactivating enzymes. Brings out flavor in carbonated beverages. Acts as a synergist for antioxidants employed in inhibiting rancidity in foods containing fats and oils.
Combinations	pure substance

Status

OFPA	
N. L. Restriction	Currently considered synthetic by NOSB.
EPA, FDA, etc	FDA -GRAS
Directions	
Safety Guidelines	Eye irritant, dust may cause mild respiratory irritation.
State Differences	
Historical status	Always been allowed in organic processing and considered natural.
International status	Allowed by IFOAM, EU and Codex.

5.

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions Not Applicable

2119(m)2: toxicity & persistence Not Applicable

2119(m)3: manufacture & disposal consequences

Microbial fermentation --Clarification --Precipitation --Dissolution --Crystallization --Drying --Sifting --packaging.
The NOSB judged that citric acid produced by natural fermentation of carbohydrate substrates and purified by the lime-sulfuric method is synthetic because the citric acid comes into contact with lime and sulfuric acid and because of the chemical change from citric acid to calcium citrate and then back to citric acid during purification.
Biomass residuals are usually recycled as animal feeds and for agriculture.

2119(m)4: effect on human health

Material has been affirmed as GRAS by FDA for use in foods. The amount of citrate added to foods by food processors is about 500 mg per person per day. This amount occurs naturally in 2 ounces of orange juice and does not constitute a significant addition to the total body load.

Long term oral over exposure may cause damage to tooth enamel. Considered an irritant to eyes and respiratory system during manufacture and handling. Recommended use of eye and respiratory protection during handling. Oral LD50 (rat) 11,700 mg/kg; dermal (acute) tested on skin of rabbit 500mg/24 hr moderate; eye 750 mg/24hr severe. FDA tests show no effect on reproduction, teratogenicity or oncogenicity in rats.

2119(m)5: agroecosystem biology Not Applicable

2119(m)6: alternatives to substance

Lactic acid (has some taste problems and not used in infant foods).
Vinegar (strange taste in some foods).
Citrus juices.

2119(m)7: Is it compatible?

Compatible

References

1. FDA. 1977. Evaluation of the health aspects of citric acid, sodium citrate, potassium citrate, calcium citrate, ammonium citrate, triethyl citrate, isopropyl citrate, and stearyl citrate as food ingredients. SCOGS-84. Life Science Research Office, 9650 Rockville Pike, Bethesda, Maryland 20014.

2. Ag Partners of Davis, *Materials Report for Citric Acid*, 1995. Organic Trade Association, Greenfield, MA

6.

MSDS for CITRIC ACID, MONOHYDRATE

Page 1

1 - PRODUCT IDENTIFICATION

PRODUCT NAME: CITRIC ACID, MONOHYDRATE
 FORMULA: $\text{HOC}(\text{COOH})(\text{CH}_2\text{COOH})_2 \text{H}_2\text{O}$ FORMULA WT: 210.14
 CAS NO.: 5949-29-1
 COMMON SYNONYMS: 2-HYDROXY-1,2,3,PROPANE-TRICARBOXYLIC ACID, MONOHYDRATE
 PRODUCT CODES: 0118,0120,0119,0110
 EFFECTIVE: 12/01/86 REVISION #02

PRECAUTIONARY LABELLING

BAKER SAF-T-DATA(TM) SYSTEM

HEALTH - 0 NONE

FLAMMABILITY - 1 SLIGHT

REACTIVITY - 0 NONE

CONTACT - 1 SLIGHT

HAZARD RATINGS ARE 0 TO 4 (0 = NO HAZARD; 4 = EXTREME HAZARD).

LABORATORY PROTECTIVE EQUIPMENT: SAFETY GLASSES; LAB COAT

PRECAUTIONARY LABEL STATEMENTS

CAUTION

MAY CAUSE IRRITATION

DURING USE AVOID CONTACT WITH EYES, SKIN, CLOTHING. WASH THOROUGHLY AFTER HANDLING. WHEN NOT IN USE KEEP IN TIGHTLY CLOSED CONTAINER.

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)

2 - HAZARDOUS COMPONENTS

COMPONENT	%	CAS NO.
CITRIC ACID, MONOHYDRATE		05949-29-1

3 - PHYSICAL DATA

BOILING POINT: N/A VAPOR PRESSURE(MM HG): N/A
 MELTING POINT: N/A VAPOR DENSITY(AIR=1): N/A
 SPECIFIC GRAVITY: 1.54 (H₂O=1) (BUTYL ACETATE=1) EVAPORATION RATE: N/A
 SOLUBILITY(H₂O): APPRECIABLE (MORE THAN 10 %) % VOLATILES BY VOLUME: 0
 APPEARANCE & ODOR: WHITE, ODORLESS POWDER.

4 - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (CLOSED CUP) N/A
 FLAMMABLE LIMITS: UPPER - N/A % LOWER - N/A %
 FIRE EXTINGUISHING MEDIA
 USE WATER SPRAY, CARBON DIOXIDE, DRY CHEMICAL OR ORDINARY FOAM.

SPECIAL FIRE-FIGHTING PROCEDURES

FIREFIGHTERS SHOULD WEAR PROPER PROTECTIVE EQUIPMENT AND SELF-CONTAINED BREATHING APPARATUS WITH FULL FACEPIECE OPERATED IN POSITIVE PRESSURE MODE.

TOXIC GASES PRODUCED: CARBON MONOXIDE, CARBON DIOXIDE

5 - HEALTH HAZARD DATA

TOXICITY TEST RESULTS AND SAFETY AND HEALTH EFFECTS ARE LISTED FOR THE ANHYDROUS PRODUCT.

TOXICITY: LD50 (ORAL-RAT)(G/KG) - 11.7

LD50 (IPR-RAT)(MG/KG) - 883

LD50 (SCU-RAT)(MG/KG) - 5500

LD50 (ORAL-MOUSE)(MG/KG) - 5040

CARCINOGENICITY: NTP: NO IARC: NO Z LIST: NO OSHA REG: NO

EFFECTS OF OVEREXPOSURE

DUST MAY IRRITATE NOSE AND THROAT.

DUST MAY CAUSE HEADACHE, COUGHING, DIZZINESS OR DIFFICULT BREATHING.

DUST MAY IRRITATE OR BURN MUCOUS MEMBRANES.

CONTACT WITH SKIN OR EYES MAY CAUSE IRRITATION.

TARGET ORGANS: EYES, SKIN

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: NONE IDENTIFIED

ROUTES OF ENTRY: INHALATION, EYE CONTACT, SKIN CONTACT

EMERGENCY AND FIRST AID PROCEDURES

INGESTION: IF SWALLOWED AND THE PERSON IS CONSCIOUS, IMMEDIATELY GIVE LARGE AMOUNTS OF WATER. GET MEDICAL ATTENTION.

INHALATION: IF A PERSON BREATHES IN LARGE AMOUNTS, MOVE THE EXPOSED PERSON TO FRESH AIR. GET MEDICAL ATTENTION.

EYE CONTACT: IMMEDIATELY FLUSH WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES. GET MEDICAL ATTENTION.

SKIN CONTACT: IMMEDIATELY WASH WITH PLENTY OF SOAP AND WATER FOR AT LEAST 15 MINUTES.

6 - REACTIVITY DATA

STABILITY: STABLE HAZARDOUS POLYMERIZATION: WILL NOT OCCUR

INCOMPATIBLES: STRONG BASES

DECOMPOSITION PRODUCTS: CARBON MONOXIDE, CARBON DIOXIDE

7 - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL OR DISCHARGE

WEAR SUITABLE PROTECTIVE CLOTHING. CAREFULLY SWEEP UP AND REMOVE.

DISPOSAL PROCEDURE

DISPOSE IN ACCORDANCE WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL ENVIRONMENTAL REGULATIONS.

8 - PROTECTIVE EQUIPMENT

VENTILATION: USE ADEQUATE GENERAL OR LOCAL EXHAUST VENTILATION TO KEEP FUME OR DUST LEVELS AS LOW AS POSSIBLE.

RESPIRATORY PROTECTION: NONE REQUIRED WHERE ADEQUATE VENTILATION CONDITIONS EXIST. IF AIRBORNE CONCENTRATION IS HIGH, USE AN APPROPRIATE RESPIRATOR OR DUST MASK.

EYE/SKIN PROTECTION: SAFETY GLASSES WITH SIDESHIELDS, NITRILE GLOVES RECOMMENDED.

8.

9 - STORAGE AND HANDLING PRECAUTIONS

SAF-T-DATA(TM) STORAGE COLOR CODE: ORANGE (GENERAL STORAGE)
SPECIAL PRECAUTIONS

KEEP CONTAINER TIGHTLY CLOSED. SUITABLE FOR ANY GENERAL CHEMICAL STORAGE
AREA.

10 - TRANSPORTATION DATA AND ADDITIONAL INFORMATION

DOMESTIC (D.O.T.)

PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

INTERNATIONAL (I.M.O.)

PROPER SHIPPING NAME CHEMICALS, N.O.S. (NON-REGULATED)

9.

05-MAY 94

PAGE 1

DOCNUM=1937

U.S. FOOD AND DRUG ADMINISTRATION
FOOD ADDITIVE SAFETY PROFILE

CITRIC ACID

CAS#: 000077929 HUMAN CONSUMPTION: 90.5367 MG/KG BW/DAY/PERSON
 FASP#: 1937 MARKET DISAPPEARANCE: 106833333.333LBS/YR
 TYPE: ASP MARKET SURVEY: 87
 NAS#: 2306 JECFA: NL-C
 FEMA#: 2306 JECFA ADI: MG/KG BW/DAY/PERSON
 GRAS#: 3 JECFA ESTABLISHED: 1979
 POTENTIAL BEVERAGE USE LAST UPDATE: 931115

FW: 192.12 DENSITY: LOGP:

STRUCTURE CATEGORIES: A6

COMPONENTS:

SYNONYMS: CITRIC ACID, ANHYDROUS
 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID
 HYDROXYTRICARBOXYLIC ACID, BETA-
 1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-
 ACIDE CITRIQUE

CHEMICAL FUNCTION: F

TECHNICAL EFFECT: PH CONTROL AGENT
 FLAVOR ENHANCER
 FLAVORING AGENT OR ADJUVANT
 LEAVENING AGENT
 SEQUESTANT
 ANTIOXIDANT
 SOLVENT OR VEHICLE
 SURFACE-ACTIVE AGENT
 ANTIMICROBIAL AGENT
 ENZYME

CFR REG NUMBERS:	173.165	172.755	182.6033
	182.1033	PART 133	PART 146
	161.190	PART 169	PART 150
	155.130	145.145	131.111
	131.112	131.136	131.144
	131.138	131.146	146.187
	150.161	150.141	166.40
	169.115	169.140	169.150
	173.160	173.280	145.131
	166.110	184.1033	

MINIMUM TESTING LEVEL: 3

COMMENTS: STUDY 1-12 FROM SCOGS-84

BOX 4A: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE RAT OR MOUSE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
 SPECIES: RAT LEL: 4670 MG/KG BW/DAY
 EFFECTS: CHOLESTEROL DECREASE
 GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
 ORGAN WEIGHT DECREASE
 CELLULAR ATROPHY
 SITES: THYMUS
 SPLEEN
 COMMENTS: MALES ONLY
 SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
 DATA FROM SCOGS-84

10.

05 MAY 94

PAGE 2

DOCNUM=1937

BOX 4C: LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES

STUDY: 4 COMPLETENESS: RANKING FACTOR: 1.938E-2
 SPECIES: RAT LEL: 4670 MG/KG BW/DAY
 EFFECTS: CHOLESTEROL DECREASE
 GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
 ORGAN WEIGHT DECREASE
 CELLULAR ATROPHY
 SITES: THYMUS
 SPLEEN
 COMMENTS: MALES ONLY
 SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
 DATA FROM SCOGS-84

BOX 7: ACUTE TOXICITY INFORMATION

STUDY: 2 SOURCE: J TAKEDA RES LAB 30:25-31
 SPECIES: RAT YEAR: 1971
 LD50: 12000 MG/KG BW
 COMMENTS:
 STUDY: 1 SOURCE: J TAKEDA RES LAB 30:25-31
 SPECIES: MOUSE YEAR: 1971
 LD50: 5000 MG/KG BW
 COMMENTS:

BOX 9: ORAL TOXICITY STUDIES (OTHER THAN ACUTE)

STUDY: 3 COMPLETENESS: SOURCE: REV PORT FARM 20:41-46
 TYPE: SHORT TERM YEAR: 1970
 SPECIES: RAT LEL: 200 MG/KG BW/DAY
 DURATION: 9 DAYS HNEL:
 EFFECTS: BODY WEIGHT DECREASE
 SITES:
 COMMENTS: INITIAL DECREASE IN WEIGHT DID NOT PERSIST
 NOT USED FOR PRIORITY RANKING
 STUDY: 4 COMPLETENESS: SOURCE: J TAKEDA RES LAB 30:25-31
 TYPE: SHORT TERM YEAR: 1971
 SPECIES: RAT LEL: 4670 MG/KG BW/DAY
 DURATION: 42 DAYS HNEL: 2260 MG/KG BW/DAY
 EFFECTS: CHOLESTEROL DECREASE
 GLUTAMIC-OXALOACETIC TRANSAMINASE (SGOT/AST) INCREASE
 ORGAN WEIGHT DECREASE
 CELLULAR ATROPHY
 SITES: THYMUS SPLEEN
 COMMENTS: SLIGHT ATROPHY OF THYMUS AND SPLENIC FOLLICLES
 STUDY: 5 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED
 TYPE: SUBCHRONIC RODENT YEAR: 1945
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: 90 DAYS HNEL: 600 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: BODY WEIGHT, BLOOD, HISTOPATH AND REPRODUCTION OBSERVED
 STUDY: 6 COMPLETENESS: SOURCE: J AM PHARM ASSOC SCI ED
 TYPE: SUBCHRONIC MAMMAL (NON-RODENT) YEAR: 1945
 SPECIES: DOG LEL: > MG/KG BW/DAY
 DURATION: 112 DAYS HNEL: 1380 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: NO BEHAVIORAL, BIOCHEMICAL OR HISTOPATHOLOGICAL ABNORMALITIES
 STUDY: 10 COMPLETENESS: SOURCE: GRP 7T0195 3
 TYPE: TERATOGENICITY YEAR: 1973
 SPECIES: RAT LEL: > MG/KG BW/DAY

11.

05 MAY 94

PAGE 3

DOCNUM=1937

DURATION: 10 DAYS HNEL: 295 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 9 COMPLETENESS: SOURCE: GRP 7T0195 3
 TYPE: TERATOGENICITY YEAR: 1973
 SPECIES: MOUSE LEL: > MG/KG BW/DAY
 DURATION: 10 DAYS HNEL: 241 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: ADMINISTERED DAY 6-15 OF GESTATION

STUDY: 11 COMPLETENESS: SOURCE: GRP 7T0195 3
 TYPE: TERATOGENICITY YEAR: 1973
 SPECIES: HAMSTER LEL: > MG/KG BW/DAY
 DURATION: 5 DAYS HNEL: 272 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: ADMINISTERED DAY 6-10 OF GESTATION

STUDY: 12 COMPLETENESS: SOURCE: GRP 7T0195 3
 TYPE: TERATOGENICITY YEAR: 1973
 SPECIES: RABBIT LEL: > MG/KG BW/DAY
 DURATION: 13 DAYS HNEL: 425 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: ADMINISTERED DAY 6-18 OF GESTATION

STUDY: 8 COMPLETENESS: SOURCE: J AGRIC FOOD CHEM 5:759-760
 TYPE: RAT ONCOGENICITY YEAR: 1957
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: 728 DAYS HNEL: 2000 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS: MALES ONLY

STUDY: 7 COMPLETENESS: SOURCE: VOEDING 17:137-148
 TYPE: REPRODUCTION (3-GENERATION) YEAR: 1956
 SPECIES: RAT LEL: > MG/KG BW/DAY
 DURATION: HNEL: 800 MG/KG BW/DAY
 EFFECTS: NO EFFECTS
 SITES:
 COMMENTS:

BOX 3: GENETIC TOXICITY STUDIES

STUDY: 15 COMPLETENESS: SOURCE:
 TYPE: YEAR:
 SPECIES: LEL: MG/KG BW/DAY
 DURATION: HNEL:
 EFFECTS:
 CELLS:
 COMMENTS:

EXHIBIT B

1/23/2015

Warning Letters > Fresh Express Incorporated 10/6/10

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Fresh Express Incorporated 10/6/10



Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

Via UPS

October 6, 2010

Fernando Aguirre, President and CEO
Chiquita Brands International, Inc. and Fresh Express, Incorporated
250 East Fifth Street
Cincinnati, OR 45202

Dear Mr. Aguirre:

Starting on May 21, 2010 and ending on June 10, 2010, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 900 E. Blanco Road, Salinas, California. During this inspection, FDA investigators collected labels for your products and reviewed their labeling at

<http://www.chiquita.com>¹. Based on our review, we have concluded that your Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links at FDA's Internet home page at <http://www.fda.gov>².

Specifically, your "Pineapple Bites with Coconut" product is misbranded within the meaning of Section 403(a) of the Act [21 U.S.C. § 343(a)] in that its statement of identity, "Pineapple Bites with Coconut", is false and misleading. The ingredient statement for this product states that it is made with coconut; however, our investigation determined that this product is made with a coconut flavor spray. The characterizing flavor of your Pineapple with Coconut product must be identified in accordance with 21 CFR 101.22(i)(1)(iii) (for example, "coconut flavor").

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products are misbranded within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling bears nutrient content claims but the products do not meet the requirements for the claims.

Specifically, their labeling includes the claim "Plus ... Antioxidants." However, this claim does not include the names of the nutrients that are the subject of the claim or, alternatively, link the term "antioxidants" by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity. 21 CFR 101.54(g)(4). Your use of this antioxidant claim therefore misbrands your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

1/23/2015

Warning Letters > Fresh Express Incorporated 10/6/10

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the claim "Plus Phytonutrients." "Phytonutrients" are not nutrients for which a recommended daily intake (RDI) or daily recommended value (DRV) has been established. Therefore, nutrient content claims regarding "phytonutrients" are not authorized and further misbrand your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)]. To the extent phytonutrients are intended to be the basis for an antioxidant nutrient content claim, that use would violate FDA regulations for the same reason and because phytonutrients are not recognized as having antioxidant activity. 21 CFR 101.54(g)(1) and (2).

Both your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the statement "Only 40 Calories." This statement implies that the products are "low calorie" foods. A "low calorie" claim may be made if a food with a reference amount customarily consumed (RACC) greater than 30 grams (g) or greater than 2 tablespoons does not provide more than 40 calories per RACC. 21 CFR 101.60(b)(2)(i)(A). The RACC established for pineapple is 140 g. See 21 CFR 101.12(b) (Table 2, Fruits and Fruit Juices, All other fruits fresh, canned, or frozen).

The nutrition information for both products states that there are 40 calories per 1 piece (80 g) of product; this equals about 70 calories per RACC. Therefore, under 21 CFR 101.13(i)(2), the products are required to carry a disclaimer adjacent to the claim, e.g., "Only 40 calories per serving, not a low calorie food". Because your products fail to bear the required disclaimer, they are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The "Pineapple Bites" and "Pineapple Bites with Coconut" products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22. Further, the ingredients ascorbic acid and citric acid must be declared by their common or usual names. 21 CFR 101.4(a).

This letter is not intended to be an all-inclusive review of your firm's products and processes. It is your responsibility to ensure that your firm and your products comply with the Act and FDA, regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product or enjoin your firm from operating.

We also note that, FDA (through its contractor) obtained two samples of Fresh Express Hearts of Romaine the testing of which yielded human pathogens. One sample was found to contain *Salmonella Anatum*; another sample was found to contain *E. coli* 0157:H7. We acknowledge that you issued letters to your customers in an effort to recall affected products. However, FDA recommends that you review your firm's criteria for receipt of raw product, your procedures for ensuring that wash, flume and processing water do not contaminate your products and any other conditions and practices that may relate to the cause of the contamination.

We further acknowledge your June 25, 2010 response to the Good Manufacturing Practices violations cited in the FDA Form 483 regarding this inspection. In your response, you committed to:

- Retrain employees to replace or sanitize their gloves after contacting unsanitized surfaces;
- Include the dryer hoist controls and the equipment control panels that involve direct employee contact in your daily wash and sanitation procedures;
- Create a new storage system for aprons, gloves, and sleeve guards for times during manufacturing when they are not in use; and
- Modify your cutting surface inspection and replacement program so that cutting surfaces will be changed after every (b)(4) of use.

However, you did not provide documentation to demonstrate that these corrections have been made. You also did not address the observation that your technician improperly read the free chlorine indicator tests in the flume water. Please provide this information and documentation in your response to this Warning Letter.

In addition to the labeling issues identified above, we note that the available labeling space is at least 6" in height; therefore, the size of the nutrition information declared on these packages is not appropriate and does not meet the formatting requirements under 21 CFR 101.9(d), including hairline and footnote requirements. We note that since some of the nutrients are at insignificant levels, a shortened version of the Nutrition Facts panel may be used, e.g., the statement "Not a significant source of dietary fiber", at the bottom of the table of nutrient values as allowed under 21 CFR 101.9(c).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of

1/23/2015

Warning Letters > Fresh Express Incorporated 10/6/10

the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Please include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Darlene B. Almogela
Director of Compliance
United States Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

If you have any questions about the content of this letter please contact Sergio Chavez, Compliance Officer, at 510-337-6886.

/s/

Barbara Cassens
District Director

Page Last Updated: 10/08/2010

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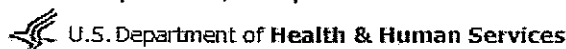
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1. <http://www.chiquita.com/>
2. <http://www.fda.gov>